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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/339,153	06/24/1999	SI LOK	97-52D1	2249

7590 06/04/2004

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/339,153	LOK ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 21-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is
5 eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 27, 2003, and claims filed August 26, 2003, have been entered..

Claim Rejections - 35 USC § 101 / 112, First Paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and
15 requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it
20 pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-38 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the previous Office action for now canceled claims 1-19 (mailed 09/17/03)
25 and as recast here.

It is stated that the present encoded polypeptide, which has not actually been expressed, is a member of the type II cytokine receptor family (p. 1, line 19), possessing several features in common with type II cytokine receptors (p. 7)., especially the interferon α receptor α chain (line 29). Because it is not know what ligand Zcytor11 binds, what the physiological outcome of
30 ligand binding would be or what disease(s) it is specifically associated with, the encoding nucleic acid does not have a specific and substantial utility. Lack of specific utility is also supported, for example, by the diverse group of tissues the encoding nucleic acid is expressed in (pancreas, colon, thymus and intestine, p. 6, lines 13-16).

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Even though the approximate chromosomal site of the encoding DNA is provided, and there is a suggestion that aberration in this area of the chromosome are sometimes associated with cancerous cells or a predisposition to cancer (p. 23, lines 4-15), *Zcytor11* DNA has not itself been shown to have any association to cancer and, especially, to a particular type of cancer, so the mapping does not provide a specific utility. There is no mutation in *Zcytor11* associated with a disease, nor is the gene linked to a disease-associated gene such that detection of *Zcytor11* in an individual provides direct information about whether that individual has a particular disease or predisposition thereto (e.g., neuroblastoma or melanoma). Additionally, because any naturally occurring human DNA can be used as a chromosomal marker, the general utility of a chromosomal tag is not specific.

For the reasons discussed above, the specification does not support a specific and substantial or well established utility for *Zcytor11* encoding polynucleotide.

Claims 21-38 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants argue (remarks filed 8/26/03) that *ZyctoR11* is a novel class II cytokine receptor and a functional receptor subunit for IL-20, which itself has been recognized to be involved with skin disorders such as psoriasis; and therefore, *Zyctor11* would be useful in treating IL-20-associated skin conditions. The argument has been fully considered, but is not persuasive. The specification does not identify IL-20 or appreciate *ZyctoR11* as part of a receptor which binds IL-20 in particular. IL-20 is not an IL-10 homolog in the sense of a species homolog. According to Dumoutier et al. ("Cutting Edge: STAT activation by IL-19, IL-20 and mda-7 through IL-20 receptor complexes of two types", J. Immunol. 2001. 167:3545-3549, previously cited by Applicant), IL-20 is a distinct IL-10-related gene. The several IL-10 "homologs" are clustered together on a chromosome, but have different expression patterns and different activities (see first and second paragraphs of Dumoutier et al.). Further, IL-20 receptor IL-20R β could not substitute for IL-10 receptor IL-10R β in IL-22 signaling, providing further

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evidence that IL-20 and IL-10 are not the same (Fig. 4). Patent 6,576,743 has no actual showing of IL-20 (apparently referred to as Zcyto10) causing, preventing or treating skin conditions such as psoriasis. The patent's showing that Zcyo10 RNA levels were higher in skin healing from a wound compared to unwounded skin (Example 4) does not support Zycotor11's use in treating skin conditions.

Applicants argue that amendment of the claims to recite that the claimed polynucleotide encodes a "cytokine receptor" polypeptide helps clarify and support utility for the invention. The argument has been fully considered, but is not persuasive. The family of cytokine receptors is large and has diverse functions, which is also true of cytokines which bind the receptors. Without specifying the type or specific function of the cytokine receptor, saying that ZcytoR11 is a cytokine receptor does not provide a specific and substantial utility or provide enablement as required under 35 USC 112, first paragraph.

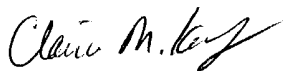
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571)272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571)272-0871. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

June 3, 2004